

Attorney Docket No. 2356.0043-0

N THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Philippe SANSONETTI et al.

Serial No.: 08/466,698

Filed: June 6, 1995

Examiner: A. Caputa

Group Art Unit:

1806

For: TRANSFORMED SHIGELLA

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

DECLARATION UNDER M.P.E.P. 608.01(p)C REGARDING DEPOSIT OF BIOLOGICAL MATERIALS

- I, PHILIPPE SANSONETTI, do hereby declare and say:
- 1. I am a citizen of France.
- 2. I am a physician and professor at Institut Pasteur in Paris, France.
- 3. On information and belief, I am a co-inventor of patent application Serial No. 08/118,100, filed September 8, 1993.
- 4. The accompanying Declaration of Mme. Danielle Berneman refers to three biological deposits designated SC501, SC506, and SC505. As described below, these deposits correspond to biological material that was deposited under different designations.

LAW OFFICES

FINNEGAN, HENDERSON. FARABOW, GARRETT & DUNNER, L. L. P. 1300 1 STREET, N. W. WASHINGTON, DC 20005 202-408-4000

Phenotype	Designation in Patent Application	Designation in Deposit Receipt	C.N.C.M.
Tox-	SC501	SC504	I-774
Aerobactin ⁻	SC506	SC602	I-1099
tox ⁻ , ent ⁻ , icsA ⁻	SC505	SC599	I-1110

5. I further declare that all statements made herein of my known own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

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Date

Philippe Sansonetti

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PATENT Attorney Docket No. 2356.0043-02000

NITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Philippe SANSONETTI et al.)
Serial No.: 08/466,698) Group Art Unit: 1806
Filed: June 6, 1995) Examiner: A. Caputa
For: METHODS FOR PRODUCING TRANSFORMED SHIGELLA (as amended))))

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

DECLARATION UNDER M.P.E.P. 608.01(p)C REGARDING DEPOSIT OF BIOLOGICAL MATERIALS

- I, MME. DANIELLE BERNEMAN, do hereby declare and say:
- 1. I am a citizen of France.
- 2. I am the Head of the Patent Section of the Institut
 Pasteur in Paris, France, to whom this patent application has
 been co-assigned, along with Institut National de la Sante et de
 la Recherche Medicale.
- 3. On information and belief, biological materials disclosed and claimed in this application were deposited with the National Collection of Cultures of Microorganisms or Collection Nationale de Cultures de Micro-organisms ("C.N.C.M.") of Institut Pasteur, 28 rue du Docteur Roux, 75724 Paris Cedex 15, France, on June 30, 1988; May 22, 1991; and June 6, 1991, respectively, under the following names and accession numbers to assure availability of the biological materials to the public:

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NAME ACCESSION NO.

SC50), Shigella dysenteriae 1 I-774

SC506, Shigella flexneri serotype 2A I-1099

SC505, Shigella dysenteriae serotype 1 I-1110

Due to the changes in the strain designation after the samples were deposited, SC501 (I-774) was referred to as SC504 in the deposit receipt, SC506 (I-1099) was referred to as SC602, and SC505 (I-1110) was referred to as SC599. This is attested to in the attached Declaration of co-inventor Philippe Sansonetti.

- 4. On information and belief, the C.N.C.M. has acquired the status of International Depository Authority within the meaning of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.
- 5. On information and belief, the C.N.C.M. has entered into an agreement with the European Patent Office (EPO) under Rule 28 of the Implementing Regulations to the European Patent Convention under which C.N.C.M. is an EPO recognized depository for viral strains.
- 6. That said biological materials have been deposited under conditions which insure that access to the cultures will be available during the pendency of the above-identified patent application to one determined by the Commissioner of Patents and Trademarks to be entitled thereto under 37 C.F.R. §1.14 and 35 U.S.C. §122.

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- 7. That no later than issuance of a patent on the aboveidentified patent application, Institut Pasteur will irrevocably
 remove any restrictions as to public availability of each
 biological material deposit, and will replace the same
 biological material deposit should it become non-viable, during
 the period that extends thirty (30) years from the date of the
 deposit, or the period of the enforceable life of the patent, or
 the period of five (5) years after the last public request for
 the deposit, whichever period is longest.
- 8. I further declare that all statements made herein of my known own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

Date: March 14th 1996

Nanielle Berneman

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